IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Antoni SANTAMARIA — Atty. Ref.: 613-97; Confirmation No.

Appl. No. 10/537,989 — TC/A.U. unknown

Filed: — Examiner: Unknown

For: ANHYDROUS CRYSTALLINE FORM OF VALACYCLOVIR HYDROCHLORIDE

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF PAU CID

I, Pau Cid, hereby declare and state as follows:

That I am familiar with the subject matter of International Patent Application PCT/EP2003/01591 filed 9 December 2003 and published as WO 2004/052892 A1 of which the above-identified U.S. patent application is a national stage entry of WO 2004/052892 A1.

That I consider myself to be the true and correct inventor of the inventions described in each of these claims and that naming Antoni Santamaria with respect to the claims of application Serial No. 10/537,989 is in error.

The error in inventorship occurred without deceptive intention on my part and I request that the Official Record be changed to list me alone as the sole inventor in respect to this application.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: NOVEMBER, 21ST 2005

Pau Cid

Claims

1. Valacyclovir hydrochloride in anhydrous crystalline form having substantially the following d-spacing pattern (in angstroms):

d-spacing
6.76
9.36
11.54
13.98
15.45
15.75
17.12
19.10
21.39
23.02
24.23
26.41
27.46
28.06

2. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 having substantially the X-ray diffraction pattern of Figure 2.

3. Valacyclovir hydrochloride in anhydrous crystalline form having substantially the characteristic infrared peaks

IR (cm^{-1}): 1686.42, 1572.60, 1533.52.

4. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 3 having substantially the characteristic infrared peaks

IR (cm^{-1}): 3377.99, 3285.87, 3197.62, 2930.92, 1749.72, 1686.42, 1631.12, 1607.17, 1572.60, 1533.52, 1476.48, 1364.98, 1298.63, 1258.79, 1248.27, 1225.22, 1132.81, 1097.06, 778.37, 759.33.

5. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 3 having substantially the infra-red absorption spectrum of Figure 1.

6. A pharmaceutical composition comprising a valacyclovir hydrochloride form as claimed in claim 1 to 5 along with one or more pharmaceutical carriers/ excipients.

7. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 for use in medicine.

8. Use of valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 in the manufacture of a medicament for use as an antiviral agent.

9. A process for the preparation of valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 comprising;

1) mixing valacyclovir hydrochloride hydrate with a substantially pure C_{1-6} lower alcohol solvent and heating the resulting suspension;

2) evaporating the solvent under reduced pressure and isolating the resulting solid.

10. The process of claim 9 wherein said solvent is ethanol.

11. The process of claim 9 or 10 wherein the suspension is heated at between 50 to 70°C for at least 12 hours.

12. The process of claim 11 wherein the suspension is heated at 60°C for 20-21 hours.

13. A process for the preparation of valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 comprising;

1) mixing valacyclovir hydrochloride hydrate with a substantially pure C_{1-6} lower alcohol solvent and adding the resulting suspension to substantially pure refluxing lower alcohol;

2) distilling off the solvent to form a suspension and maintaining the same at room temperature for at least 8 hours; and

3) isolating the resulting solid.

14. The process of claim 13 wherein the solvent and refluxing lower alcohol are ethanol.

15. The process of claim 13 or 14 wherein approximately one third of the solvent is distilled off to form said suspension.